

REMARKS

Correspondence Address

Applicants note that a change of correspondence address was filed on May 25, 2010 and appreciate future correspondences be sent to the address associated with the undersigned Customer Number.

Status of Claims

Claims 1-7 and 14-23 are currently pending in the present application. Claims 1, 6, and 17 are amended. Support for the amendment to Claims 1 and 17 can be found in the published application, for example, at paragraphs [0058], [0108], and [0109]. Claim 6 was amended to clarify its language. Thus, no new matter is introduced. Accordingly, Claims 1-7 and 14-23 are presented for examination on the merits.

Drawings

Applicants respectfully request the Examiner to acknowledge acceptance of the drawings filed on May 14, 2007.

Rejections under 35 U.S.C. § 102(b) based on Fukuda

Claims 1-6 and 14-23

The Examiner has rejected Claims 1-6 and 14-23 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,136,580 to Fukuda et al. ("Fukuda"). A claim is anticipated only if each and every element of the claim is expressly or inherently found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131.

In the Final Office Action of April 16, 2010, the Examiner argued that Claims 1-6 and 14-23 only recite two active steps comprising (1) detecting core-2 β 1,6-N-acetylglucosaminyltransferase in a sample and (2) analyzing the sample. *Final Office Action* at page 4. Moreover, the Examiner did not give weight to the "wherein" clause of Claim 1 allegedly because it merely states the results of the two active steps of the claim. *Id.* at page 5. With this interpretation, the Examiner concluded that Fukuda at column 14, line 62 – column 15,

line 66 reads on those two active steps. *Id.* Moreover, in the Advisory Action of August 5, 2010, the Examiner contends that Fukuda discloses "detecting an increased risk for recurrence fo [sic] cancer" because Fukuda "reads on comparing samples including a control and increased risks" at column 11, lines 36-45. *Advisory Action* at page 2. The Examiner further argued that the phrase "possibility of cancer recurrence" is supported by the specification but is not the same as "increased risk of recurrence."

Applicants traverse and disagree with the Examiner's analysis. First, without acquiescing to the Examiner's interpretation that "possibility of cancer recurrence" and "increased risk of recurrence" are not the same, Claims 1 and 17 have been amended to reflect detecting or predicting the possibility of cancer recurrence.

Claim 1 has been amended to recites *three* active elements including detecting the level of core-2 β 1,6-N-acetylglucosaminyltransferase polypeptides in a sample collected from a biological organism, wherein the sample comprises cancer cells; comparing the level to a normal control level; and detecting a high possibility of cancer recurrence if a higher level of core-2 β 1,6-N-acetylglucosaminyltransferase polypeptides compared to normal is found.

Claims 17-23 also have *three* active elements including providing a biological sample from the subject, wherein the sample comprises cancer cells; contacting the biological sample with an antibody having specificity for core-2 β 1,6-N-acetylglucosaminyltransferase polypeptides; and determining whether the antibody binds to the core-2 β 1,6-N-acetylglucosaminyltransferase polypeptides at a higher level than normal controls, wherein a higher level of binding is indicative of a high possibility of cancer recurrence.

The cited portions of Fukuda do not teach each and every element of independent Claims 1 and 17 as amended. Fukuda at column 14, line 62 - column 15, line 66 describes use of an antibody to detect C2GnT-M in a sample, but does not disclose what the sample is or what use the antibody is for other than detection of C2GnT-M or targeting cells that express C2GnT-M. Although Fukuda at column 11, lines 36-45 discloses that increased or decreased C2GnT-M expression compared to a control sample can indicate an increased risk of a pathology such as tumor invasion or metastasis, this cited passage of Fukuda fails to disclose a possibility for cancer recurrence as reflected in the claims. Tumor invasion and metastasis are characteristics of a tumor that are not necessarily linked to cancer recurrence.

The Examiner apparently assumes that Fukuda's disclosure of tumor invasion and metastasis inherently discloses cancer recurrence. However, this assumption is factually incorrect because invasion and metastasis of a tumor do not always and necessarily entail recurrence of cancer. Whereas invasion and metastasis refer to cancer cells spreading from a primary organ to a secondary organ, recurrence refers to cancer that returns to the same organ after initial regression, treatment, or resection. As such, Fukuda does not directly or inherently disclose each and every limitation and thus fails to anticipate Claims 1-6 and 14-23.

In the Advisory Action, the Examiner further argued that Claims 17-23 do not recite a cancer sample and Fukuda at column 7, lines 5-15 nevertheless states that a sample is "any biological fluid, cell, tissue, organ or portion thereof that includes or potentially includes cell expressing C2GnT-M." *Advisory Action* at page 2. The Examiner concludes, "It is clear C2GnT-M is expressed in cancer." As an initial matter, Applicants note that Claim 17 has been amended to reflect that the sample comprises cancer cells. Moreover, Fukuda's general teaching that *anything* can serve as a sample cannot reasonably be construed as either a direct or inherent disclosure of cancer cells in particular. Nevertheless, Fukuda still fails to disclose predicting the possibility of cancer recurrence as explained above. At least for this reason, Fukuda does not anticipate Claims 17-23, either directly or inherently, and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Based on the foregoing, Applicants request withdrawal of the rejections of Claims 1-6 and 14-16 under 35 U.S.C. § 102(b).

Claim 7

Applicants note that Claim 7 is not presently rejected and respectfully request allowance of the claim.

The Pending Claims are Non-obvious over the Cited Art

The pending claims are directed to a new use for an antibody that detects C2-GnT polypeptides. Applicants discovered that cancer recurrence can be detected or predicted by the claimed inventive methods prior to commencing unnecessary medical treatments such as tissue resection or other therapy. The claimed methods provide information as to whether it is

medically necessary or advantageous to proceed with a particular therapeutic course of action. For example, by allowing cancer recurrence to be detected or predicted, the inventive methods can guide an informed therapeutic course of action, including whether cancer tissue resection or total tissue resection is recommendable relative to the risk of cancer recurrence, or whether a need to select another therapy exists.

By contrast, the cited art merely discloses an antibody against C2-GnT-M. Disclosure of the antibody alone could not predictably lead to the inventive methods of detecting or predicting cancer recurrence, which provide useful information for choosing a therapeutic course before unnecessary treatment or surgery is undertaken. As such, Applicants submit that pending Claims 1-7 and 14-23 are non-obvious over the cited art.

Conclusion

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action and Advisory Action. In light of the above amendments to Claims 1 and 17, and remarks concerning the remaining pending claims, Applicants respectfully request issuance of a Notice of Allowance. If the Examiner has any questions which may be answered by telephone, the Examiner is invited to call the undersigned directly.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.


Application No.: 10/549,811
Filing Date: September 14, 2006

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 7, 2010

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